

## CLAIMS

What is claimed is:

1. An integrated medication delivery system for delivering medication to a patient wherein said system is suitable for complete sterilization by a sterilization fluid, said system comprising:

a base housing;

a medication reservoir disposed about said base housing for storing the medication to be delivered to the patient;

a pump assembly supported by said base housing for delivering the medication to the patient, said pump assembly comprising a pump housing having a pump inlet and a pump outlet, wherein said pump inlet and said pump outlet alternate between an open and a closed state to deliver the medication to the patient;

a port extending from said base housing, said port being in fluid communication with said medication reservoir and said pump assembly during sterilization to provide access for the sterilization fluid to flow into said medication reservoir and said pump assembly; and

an actuator disposed in said base housing and operatively engaging said pump inlet and said pump outlet to retain both said pump inlet and said pump outlet in said open state during sterilization such that the sterilization fluid can penetrate into said medication reservoir, said pump inlet, said pump housing, and said pump outlet to completely sterilize said system.

2. A system as set forth in claim 1 further comprising a first pinch lever disposed at said pump inlet that is normally-biased to maintain said pump inlet in

said closed state, and a second pinch lever disposed at said pump outlet that is normally-biased to maintain said pump outlet in said closed state.

3. A system as set forth in claim 2 wherein said actuator moves said first pinch lever away from said pump inlet to retain said pump inlet in said open state during sterilization and moves said second pinch lever away from said pump outlet to retain said pump outlet in said open state during sterilization.

4. A system as set forth in claim 1 wherein said actuator is operatively disengaged from said pump inlet and said pump outlet during delivery of the medication to the patient such that said pump inlet and said pump outlet can alternate between said open and closed states to deliver the medication the patient.

5. A system as set forth in claim 1 further comprising an electronic controller mounted to said base housing for controlling an amount of the medication to be delivered to the patient, wherein said electronic controller remains mounted to said base housing during sterilization.

6. A system as set forth in claim 5 further comprising an electronic display and at least one control button mounted to said base housing for interacting with said electronic controller to control the amount of the medication to be delivered to the patient, wherein said electronic display and said control button remain mounted to said base housing during sterilization.

7. A system as set forth in claim 1 further comprising a fluid flow path for the sterilization fluid defined between said port, said medication reservoir, and said pump assembly such that the flow of the sterilization fluid through said fluid flow path is continuous during sterilization of said system.

8. A system as set forth in claim 2 further comprising;

a medication inlet tube connected between said port and said pump inlet to provide access for the sterilization fluid to flow from said port into said pump assembly; and

5 a medication outlet tube connected between said pump outlet and said port to provide access for the sterilization fluid to flow from said pump assembly into said port.

9. A system as set forth in claim 8 wherein said first pinch lever is normally-biased to pinch said medication inlet tube such that said pump inlet is  
10 maintained in said closed state, and said second pinch lever is normally-biased to pinch said medication outlet tube such that said pump outlet is maintained in said closed state.

10. A system as set forth in claim 9 wherein said actuator moves said first pinch lever away from said medication inlet tube such that said pump inlet  
15 remains in said open state during sterilization and moves said second pinch lever away from said medication outlet tube such that said pump outlet remains in said open state during sterilization.

11. A system as set forth in claim 2 wherein said actuator comprises a base portion and first and second engagement arms extending from said base  
20 portion, said first engagement arm of said actuator engaging said first pinch lever to move said first pinch lever away from said pump inlet to retain said pump inlet in said open state during sterilization, and said second engagement arm of said actuator

engaging said second pinch lever to move said second pinch lever away from said pump outlet to retain said pump outlet in said open state during sterilization.

12. A system as set forth in claim 11 further comprising a plunger disposed within said port for displacing said actuator from said engagement with  
5 said first and second pinch levers after sterilization such that said pump inlet and said pump outlet can alternate between said open and said closed state to deliver the medication to the patient.

13. A system as set forth in claim 12 wherein said actuator further comprises an actuation arm extending from said base portion between said first and  
10 second engagement arms, said actuation arm being engaged by said plunger to displace said actuator from said engagement with said first and second pinch levers after sterilization.

14. A system as set forth in claim 13 further comprising an electronic controller mounted to said base housing for controlling an amount of the medication  
15 to be delivered to the patient, wherein said electronic controller remains mounted to said base housing during sterilization.

15. A system as set forth in claim 14 further comprising a control contact disposed at a distal end of said actuation arm away from said base portion, said control contact activating said electronic controller when said actuator is disengaged  
20 from said first and second pinch levers thereby permitting said pump assembly to operate for delivering the medication to the patient.

16. A system as set forth in claim 1 further comprising a plunger disposed within said port for displacing said actuator from said operative

engagement with said pump inlet and said pump outlet after sterilization such that said pump inlet and said pump outlet can alternate between said open and said closed state to deliver the medication the patient.

17. A system as set forth in claim 1 wherein said actuator comprises a  
5 base portion and at least one engagement arm extending from said base portion, said at least one engagement arm of said actuator operatively engaging said pump assembly to retain said pump inlet and said pump outlet in said open state during sterilization.

18. A system as set forth in claim 17 further comprising a plunger  
10 disposed within said port for displacing said actuator from said operative engagement with said pump assembly after sterilization such that said pump inlet and said pump outlet can alternate between said open and said closed state to deliver the medication the patient.

19. A system as set forth in claim 18 wherein said actuator further  
15 comprises an actuation arm extending from said base portion between said first and second engagement arms, said actuation arm being engaged by said plunger to displace said actuator from said operative engagement with said pump assembly after sterilization.

20. A pump assembly for an integrated medication delivery system, wherein said pump assembly delivers medication to a patient and is suitable to prevent inadvertent delivery of the medication to the patient, said assembly comprising:

5 a pump housing having a pump inlet and a pump outlet;

a first pinch lever disposed at said pump inlet, said first pinch lever being moveable between an open position and a closed position to control a flow of the medication into said pump housing through said pump inlet;

10 a second pinch lever disposed at said pump outlet, said second pinch lever being moveable between an open position and a closed position to control a flow of the medication from said pump housing through said pump outlet;

a motor operatively engaging said first and second pinch levers for moving said first and second pinch levers into said open position such that the medication can be delivered to the patient; and

15 at least one biasing device engaging at least one of said first and second pinch levers and working in conjunction with said motor to normally bias at least one of said first and second pinch levers into said closed position during delivery of the medication to the patient and to maintain at least one of said first and second pinch levers in said closed position during a failure of said motor to prevent the  
20 inadvertent delivery of the medication to the patient.

21. A pump assembly as set forth in claim 20 further comprising a cam shaft supported on said pump housing and geared to said motor to operatively engage said motor with said first and second pinch levers.

22. A pump assembly as set forth in claim 21 wherein each of said first and second pinch levers comprise a cam follower, said cam followers being engaged by said cam shaft for alternating movement of said first and second pinch levers between said open and closed positions such that the medication can be delivered to the patient.

23. A pump assembly as set forth in claim 20 further comprising a piston disposed in said pump housing, said motor moving said piston within said pump housing to draw the medication into said pump housing when said first pinch lever is in said open position and said second pinch lever is in said closed position, and to displace the medication from said pump housing when said first pinch lever is in said closed position and said second pinch lever is in said open position.

24. A pump assembly as set forth in claim 23 wherein said piston comprises an actuation end and a pumping end with a diaphragm seal disposed at said pumping end.

25. A pump assembly as set forth in claim 24 wherein said actuation end of said piston comprises at least one slot, and said pump housing comprises at least one detent engaging said at least one slot to prevent unwanted rotation of said piston as said piston is moved within said pump housing by said motor.

26. A pump assembly as set forth in claim 24 wherein said cam shaft supports first and second outside cams and an inside cam disposed between said first and second outside cams, said first outside cam engaging said first pinch lever to move said first pinch lever between said open and closed position, said inside cam engaging said actuation end of said piston to move said piston within said pump

housing, and said second outside cam engaging said second pinch lever to move said second pinch lever between said open and closed positions.

27. A pump assembly as set forth in claim 26 wherein each of said first and second pinch levers comprise a cam follower, said cam follower of said first  
5 pinch lever being engaged by said first outside cam for alternating movement of said first pinch lever between said open and closed positions, and said cam follower of said second pinch lever being engaged by said second outside cam for alternating movement of said second pinch lever between said open and closed positions.

28. A pump assembly as set forth in claim 27 wherein each of said first  
10 and second outside cams comprise internal cam surfaces, said cam follower of said first pinch lever riding within said internal cam surface of said first outside cam for alternating movement of said first pinch lever between said open and closed positions, and said cam follower of said second pinch lever riding within said internal cam surface of said second outside cam for alternating movement of said  
15 second pinch lever between said open and closed positions.

29. A pump assembly as set forth in claim 26 further comprising an indicating flag extending from one of said first and second outside cams for monitoring an amount of the medication that has been delivered to the patient.

30. A pump assembly as set forth in claim 29 in combination with a  
20 sensor optically-coupled with said indicating flag to count revolutions of said indicating flag for monitoring the amount of the medication that has been delivered to the patient.



31. A pump assembly as set forth in claim 20 wherein said motor moves said first and second pinch levers into said open position despite said bias of said at least one biasing device such that the medication can be delivered to the patient.

32. A pump assembly as set forth in claim 20 in combination with;  
5 a medication inlet tube adapted to provide access for the medication to flow into said pump inlet; and

a medication outlet tube adapted to provide access for the medication to flow from said pump outlet;

wherein said at least one biasing device engages said first pinch lever to  
10 normally-bias said first pinch lever into said closed position to pinch said medication inlet tube, and said at least one biasing device engages said second pinch lever to normally-bias said second pinch lever into said closed position to pinch said medication outlet tube.

33. A pump assembly as set forth in claim 20 in combination with an  
15 actuator engaging said first and second pinch levers to retain both said first and second pinch levers in said open position for sterilization despite said bias of said at least one biasing device.

34. A pump assembly as set forth in claim 20 wherein said at least one biasing device is further defined as a compression spring.

20 35. A pump assembly as set forth in claim 20 wherein said at least one biasing device comprises a first and a second biasing device, said first biasing device engaging said first pinch lever and said second biasing device engaging said second pinch lever to maintain said first and second pinch levers in said closed position

during a failure of said motor to prevent the inadvertent delivery of the medication to the patient.

36. A pump assembly as set forth in claim 26 wherein each of said first and second outside cams comprise a plurality of slits along an outer circumference  
5 of said cams to confirm dimensional tuning of said cams during assembly.

37. A pump assembly as set forth in claim 26 wherein at least one of said first and second outside cams comprises an assembly slot defined within an outer circumference of said cams to facilitate assembly of said pump assembly.

38. A port assembly for an integrated medication delivery system that includes a medication reservoir and a pump assembly, wherein said port assembly enables various fluids to flow into, from, and within the integrated medication delivery system, said port assembly comprising:

5 an elongated housing comprising a proximate end, a distal end, and an interior wall defining a fluid chamber between said ends, said proximate end of said housing extending from the integrated medication delivery system to provide access for the fluid to flow both into and from the integrated medication delivery system;

a first fluid connector extending from said housing for allowing the fluid to  
10 flow from said fluid chamber into the pump assembly;

a second fluid connector extending from said housing for allowing the fluid to flow from the pump assembly into said fluid chamber;

a third fluid connector extending from said housing for allowing the fluid to flow between said fluid chamber and the medication reservoir; and

15 a plunger disposed in said fluid chamber and being moveable in said fluid chamber between;

an off-position where said first, second, and third fluid connectors are isolated from said proximate end of said housing by said plunger to prevent the flow of fluid,

20 a fill-position where said first and third fluid connectors are in fluid communication with said proximate end of said housing thereby providing a fluid flow path between said proximate end of said housing, the medication reservoir, and

the pump assembly such that the fluid can be filled through said proximate end of said housing and into the medication reservoir and the pump assembly, and

a fluid delivery-position where said first, second, and third fluid connectors are in fluid communication with said proximate end of said housing and with each other for supplying the pump assembly and for delivering the fluid to a patient.

39. A port assembly as set forth in claim 38 wherein said plunger comprises a length, a circumference, and a plurality of seats disposed along said length and about said circumference, said seats extending outwardly from said circumference to said interior wall of said housing for segregating said fluid chamber of said housing.

40. A port assembly as set forth in claim 39 further comprising a fluid passage defined between each of said seats and said interior wall of said housing for controlling the flow of fluid within said port assembly.

41. A port assembly as set forth in claim 40 further comprising a seal disposed about each of said seats for sealing said fluid passages from one another.

42. A port assembly as set forth in claim 41 further comprising at least one leak rib extending at least partially along said interior wall of said elongated housing to selectively cause at least one of said seals to leak when said plunger is in said fill-position.

43. A port assembly as set forth in claim 41 wherein said seals are O-rings.

44. A port assembly as set forth in claim 40 wherein said plunger is at least partially hollow to define an internal fluid bore extending within said plunger between said seats.

45. A port assembly as set forth in claim 44 wherein said plunger further  
5 comprises an access end and an actuation end, and said internal fluid bore extends from said access end, where the fluid flows into and from said internal fluid bore, toward said actuation end.

46. A port assembly as set forth in claim 45 wherein said internal fluid  
bore comprises a fluid duct in fluid communication with one of said fluid passages  
10 such that the fluid can flow into and from said internal fluid bore.

47. A port assembly as set forth in claim 46 wherein said plurality of  
seats are further defined as a first, second, third, and fourth seat, wherein said first  
seat is disposed toward said access end of said plunger, said fourth seat is disposed  
toward said actuation end of said plunger, and said second and third seats are  
15 disposed successively between said first and fourth seats.

48. A port assembly as set forth in claim 47 wherein said fluid passages  
are further defined as a first, second, and third fluid passage, wherein said first fluid  
passage is defined between said first and second seats and said interior wall, said  
second fluid passage is defined between said second and third seats and said interior  
20 wall, and said third fluid passage is defined between said third and fourth seats and  
said interior wall.

49. A port assembly as set forth in claim 48 further comprising a first  
seal disposed about said first seat for sealing said first fluid passage from said access

end of said plunger, a second seal disposed about said second seat for sealing said first and second fluid passages from one another, a third seal disposed about said third seat for sealing said second and third fluid passages from one another, and a fourth seal disposed about said fourth seat for sealing said third fluid passage from said actuation end of said plunger.

50. A port assembly as set forth in claim 49 further comprising at least one leak rib extending along said interior wall of said elongated housing from said proximate end toward said distal end to selectively cause said first seal to leak when said plunger is in said fill-position.

10 51. A port assembly as set forth in claim 48 wherein said internal fluid bore extends within said plunger from said access end to said third seat.

52. A port assembly as set forth in claim 51 wherein said fluid duct is in fluid communication with said second fluid passage defined between said second and third seats and said interior wall such that the fluid can flow into and from said internal fluid bore at said second fluid passage.

15 53. A port assembly as set forth in claim 52 wherein said first, second, and third fluid connectors are isolated from said proximate end of said housing and from said access end of said plunger by said first, second, and third seats when said plunger is in said off-position.

20 54. A port assembly as set forth in claim 52 wherein said first and third fluid connectors are in fluid communication with said proximate end of said housing and with said access end of said plunger through said second fluid passage and said fluid duct of said internal fluid bore when said plunger is in said fill-position such

that the fluid can be filled through said access end of said plunger, through said internal fluid bore and said fluid duct, and into the medication reservoir and the pump assembly.

55. A port assembly as set forth in claim 54 wherein said second fluid  
5 connector is isolated from said proximate end of said housing, from said access end of said plunger, and from said first and third fluid connectors by said third and fourth seats when said plunger is in said fill-position.

56. A port assembly as set forth in claim 52 wherein said second fluid  
connector is in fluid communication with said proximate end of said housing and  
10 with said access end of said plunger through said second fluid passage and said fluid duct of said internal fluid bore when said plunger is in said fluid delivery-position for delivering the fluid from the pump assembly to the patient.

57. A port assembly as set forth in claim 56 wherein said first and third  
fluid connectors are isolated from said proximate end of said housing and said  
15 access end of said plunger by said first and second seats, but are in fluid communication with the medication reservoir through said first fluid passage when said plunger is in said fluid delivery-position for supplying the pump assembly with the fluid.

58. A port assembly as set forth in claim 48 wherein said first and third  
20 fluid connectors are aligned with said third fluid passage when said plunger is in said off-position, with said second fluid passage when said plunger is in said fill-position, and with said first fluid passage when said plunger is in said fluid delivery-position.

59. A port assembly as set forth in claim 45 further comprising a biasing device disposed about said actuation end of said plunger for biasing said plunger into said off-position.

60. A port assembly as set forth in claim 38 in combination with a fluid  
5 filling device that engages said proximate end of said housing to automatically move said plunger into said fill-position for filling the medication reservoir and the pump assembly.

61. A port assembly as set forth in claim 60 wherein said fluid filling device is a syringe that moves said plunger into said fill-position for filling the  
10 medication reservoir and the pump assembly.

62. A port assembly as set forth in claim 60 wherein said fluid filling device is a fluid cap that moves said plunger into said fill-position to enable a sterilization fluid to penetrate into the medication reservoir and the pump assembly.

63. A port assembly as set forth in claim 45 in combination with a  
15 syringe engaging said access end of said plunger to automatically move said plunger into said fill-position for filling the medication reservoir and the pump assembly through said internal fluid bore.

64. A port assembly as set forth in claim 38 in combination with an infusion tube set comprising a fluid end and a patient end wherein said fluid end of  
20 said tube set engages said proximate end of said housing to automatically move said plunger into said fluid delivery-position for delivering the fluid to the patient.

65. A port assembly as set forth in claim 45 in combination with an infusion tube set comprising a fluid end and a patient end wherein said fluid end of



said tube set engages said access end of said plunger to automatically move said plunger into said fluid delivery-position for delivering the fluid to the patient.

66. A blockage detection system for an integrated medication delivery system used for delivering medication to a patient, wherein said blockage detection system detects a blockage in a flow of the medication to the patient and comprises:

a base housing;

5 a medication reservoir disposed about said base housing for storing the medication to be delivered to the patient;

a port extending from said base housing to provide access for the medication to flow to the patient;

a pump assembly supported by said base housing and in fluid  
10 communication with said medication reservoir for delivering the medication to the patient;

a medication outlet tube mounted to said base housing and connected between said pump assembly and said port to provide access for the medication to flow from said pump assembly into said port and to the patient, wherein said outlet  
15 tube has a diameter that is contractible and expandable between a normal condition and an expanded condition in response to variations in pressure resulting from the flow of the medication from said medication reservoir through said pump assembly into said port and to the patient;

an electronic controller mounted to said base housing adjacent said outlet  
20 tube; and

a detection film disposed between said electronic controller and said outlet tube, said detection film being in contact with said outlet tube and remaining spaced from said electronic controller when said diameter of said outlet tube is in said

normal condition, and said detection film being in contact with said outlet tube and contacting said electronic controller to activate said electronic controller when said diameter of said outlet tube is in said expanded condition in response to increased pressure resulting from the blockage in the flow of the medication to the patient.

5           67.     A blockage detection system as set forth in claim 66 wherein said detection film is mounted to said electronic controller, yet remains at least partially-spaced from said electronic controller when said diameter of said outlet tube is in said normal condition.

          68.     A blockage detection system as set forth in claim 67 further  
10    comprising an adhesive layer for mounting said detection film to said electronic controller and for spacing said detection film from said electronic controller when said diameter of said outlet tube is in said normal condition.

          69.     A blockage detection system as set forth in claim 66 further  
15    comprising a support platform mounted on said base housing for supporting said outlet tube on said base housing.

          70.     A blockage detection system as set forth in claim 69 wherein said support platform comprises at least one tube slot to house said diameter of said outlet tube.

          71.     A blockage detection system as set forth in claim 70 wherein said  
20    outlet tube is mounted in said tube slot such that at least a portion of said diameter of said outlet tube is exposed to said detection film.

72. A blockage detection system as set forth in claim 66 wherein said detection film is conductive for activating said electronic controller when said diameter of said outlet tube is in said expanded condition.

73. A blockage detection system as set forth in claim 66 wherein said  
5 electronic controller deactivates said pump assembly to prevent delivery of the medication to the patient when said diameter of said outlet tube is in said expanded condition due to blockage in the flow of the medication to the patient.

74. A blockage detection system as set forth in claim 66 further  
10 comprising an alarm activated by said electronic controller to indicate the blockage when said diameter of said outlet tube is in said expanded condition due to blockage in the flow of the medication to the patient.

75. A blockage detection system as set forth in claim 66 further  
comprising an electronic switch embedded in said electronic controller between said  
15 electronic controller and said detection film wherein said detection film contacts said electronic switch to activate said electronic controller when said diameter of said outlet tube is in said expanded condition.

76. A blockage detection system as set forth in claim 66 wherein said  
electronic controller deactivates said pump assembly when said diameter of said  
outlet tube is in said expanded condition for more than at least one cycle of said  
20 pump assembly.

77. A blockage detection system for an integrated medication delivery system used for delivering medication to a patient, wherein said blockage detection system detects a blockage in a flow of the medication to the patient and comprises:

a base housing;

5 a medication reservoir disposed about said base housing for storing the medication to be delivered to the patient;

a port extending from said base housing to provide access for the medication to flow to the patient;

a pump assembly supported by said base housing and in fluid  
10 communication with said medication reservoir for delivering the medication to the patient;

an electronic controller mounted to said base housing;

a medication outlet tube mounted to said base housing and connected between said pump assembly and said port to provide access for the medication to  
15 flow from said pump assembly into said port and to the patient, wherein said outlet tube has a diameter that is contractible and expandable between a normal condition, where said outlet tube is spaced from said electronic controller, and an expanded condition, where said outlet tube is in contact with said electronic controller, in response to variations in pressure resulting from the flow of the medication from  
20 said medication reservoir through said pump assembly into said port and to the patient; and

a coating applied to said outlet tube, said coating activating said electronic controller when said diameter of said outlet tube is in said expanded condition in

response to increased pressure resulting from the blockage in the flow of the medication to the patient.

78. A blockage detection system as set forth in claim 76 wherein said coating is conductive.

5 79. A blockage detection system as set forth in claim 77 wherein said coating that is applied to said outlet tube is formed of conductive carbon.

80. A blockage detection system as set forth in claim 76 further comprising a support platform mounted on said base housing for supporting said outlet tube on said base housing.

10 81. A blockage detection system as set forth in claim 79 wherein said support platform comprises at least one tube slot to house said diameter of said outlet tube.

82. A blockage detection system as set forth in claim 80 wherein said outlet tube is mounted in said tube slot such that at least a portion of said coating is  
15 exposed beyond said tube slot.

83. A blockage detection system as set forth in claim 76 wherein said electronic controller deactivates said pump assembly to prevent delivery of the medication to the patient when said diameter of said outlet tube is in said expanded condition due to blockage in the flow of the medication to the patient.

20 84. A blockage detection system as set forth in claim 76 further comprising an alarm activated by said electronic controller to indicate the blockage when said diameter of said outlet tube is in said expanded condition due to blockage in the flow of the medication to the patient.

85. A blockage detection system as set forth in claim 76 further comprising an electronic switch embedded in said electronic controller that is activated when said diameter of said outlet tube is in said expanded condition in response to increased pressure resulting from the blockage in the flow of the medication to the patient.

86. A blockage detection system as set forth in claim 77 wherein said electronic controller deactivates said pump assembly when said diameter of said outlet tube is in said expanded condition for more than at least one cycle of said pump assembly.

87. An empty detection system for an integrated medication delivery system used for delivering medication to a patient, wherein said empty detection system determines when a supply of the medication has been depleted and comprises:

5 a base housing;

a medication reservoir disposed about said base housing for storing the supply of the medication to be delivered to the patient;

a port extending from said base housing to provide access for the medication to flow to the patient;

10 a pump assembly supported by said base housing and in fluid communication with said medication reservoir for delivering the medication to the patient;

a medication inlet tube mounted to said base housing and connected between said medication reservoir and said pump assembly to provide access for the medication to flow from said medication reservoir into said pump assembly and to the patient, wherein said inlet tube has a diameter that is contractible and expandable between a normal condition and a collapsed condition in response to variations in pressure resulting from a lack of flow of the medication from said medication reservoir into said pump assembly and to the patient;

20 an electronic controller mounted to said base housing adjacent said inlet tube; and

a detection film disposed between said electronic controller and said inlet tube, said detection film being in contact with said inlet tube and contacting said



electronic controller to activate said electronic controller when said diameter of said inlet tube is in said normal condition, and said detection film becoming spaced from said electronic controller to deactivate said electronic controller when said diameter of said inlet tube is in said collapsed condition in response to the lack of flow of the medication resulting from the supply of the medication being depleted.

88. An empty detection system as set forth in claim 87 further comprising an electronic switch embedded in said electronic controller between said electronic controller and said detection film, wherein said detection film contacts said electronic switch to activate said electronic controller when said diameter of said inlet tube is in said normal condition and said detection film becomes spaced from said electronic switch to deactivate said electronic controller when said diameter of said inlet tube is in said collapsed condition.

89. An empty detection system as set forth in claim 88 wherein said detection film comprises a film base portion and a cantilever portion extending from said film base portion to contact said electronic switch in said normal condition.

90. An empty detection system as set forth in claim 89 wherein said film base portion of said detection film is mounted to said electronic controller away from said electronic switch.

91. An empty detection system as set forth in claim 89 wherein said cantilever portion of said detection film becomes spaced from said electronic controller to deactivate said electronic controller when said diameter of said inlet tube is in said collapsed condition.

92. An empty detection system as set forth in claim 87 further comprising a support platform mounted on said base housing for supporting said inlet tube on said base housing.

93. An empty detection system as set forth in claim 92 wherein said  
5 support platform comprises at least one tube slot to house said diameter of said inlet tube.

94. An empty detection system as set forth in claim 93 wherein said inlet tube is mounted in said tube slot such that at least a portion of said diameter of said inlet tube is exposed to said detection film.

10 95. An empty detection system as set forth in claim 87 wherein said detection film is conductive for activating said electronic controller when said diameter of said inlet tube is in said normal condition.

96. An empty detection system as set forth in claim 87 further comprising an alarm activated by said electronic controller to indicate the lack of  
15 flow of the medication when said diameter of said inlet tube is in said collapsed condition due to the lack of flow of the medication to the patient.

97. An empty detection system as set forth in claim 87 wherein said electronic controller deactivates said pump assembly when said diameter of said inlet tube is in said collapsed condition due to the lack of flow of the medication to  
20 the patient.

98. An empty detection system as set forth in claim 87 wherein said electronic controller deactivates said pump assembly when said diameter of said

inlet tube is in said collapsed condition for more than at least one cycle of said pump assembly.

99. An empty detection system for an integrated medication delivery system used for delivering medication to a patient, wherein said empty detection system determines when a supply of the medication has been depleted and comprises:

5 a base housing;

a medication reservoir disposed about said base housing for storing the supply of the medication to be delivered to the patient;

a port extending from said base housing to provide access for the medication to flow to the patient;

10 a pump assembly supported by said base housing and in fluid communication with said medication reservoir for delivering the medication to the patient;

an electronic controller mounted to said base housing;

a medication inlet tube mounted to said base housing and connected between  
15 said medication reservoir and said pump assembly to provide access for the medication to flow from said medication reservoir into said pump assembly and to the patient, wherein said inlet tube has a diameter that is contractible and expandable between a normal condition, where said inlet tube is in contact with said electronic controller, and a collapsed condition, where said inlet tube becomes spaced from  
20 said electronic controller, in response to variations in pressure resulting from a lack of flow of the medication from said medication reservoir into said pump assembly and to the patient; and

a coating applied to said inlet tube, said coating contacting said electronic controller to activate said electronic controller when said diameter of said inlet tube is in said normal condition, and said coating becoming spaced from said electronic controller to deactivate said electronic controller when said diameter of said inlet tube is in said collapsed condition in response to the lack of flow of the medication resulting from the supply of the medication being depleted.

100. An empty detection system as set forth in claim 99 wherein said coating is conductive.

101. An empty detection system as set forth in claim 100 wherein said coating that is applied to said outlet tube is formed of conductive carbon.

102. An empty detection system as set forth in claim 99 further comprising an electronic switch embedded in said electronic controller that is activated when said diameter of said inlet tube is in said normal condition and that is deactivated when said inlet tube is in said collapsed condition.

103. An empty detection system as set forth in claim 99 further comprising a support platform mounted on said base housing for supporting said inlet tube on said base housing.

104. An empty detection system as set forth in claim 103 wherein said support platform comprises at least one tube slot to house said diameter of said inlet tube.

105. An empty detection system as set forth in claim 104 wherein said inlet tube is mounted in said tube slot such that at least a portion of said coating is exposed beyond said tube slot.

106. An empty detection system as set forth in claim 99 further comprising an alarm activated by said electronic controller to indicate the lack of flow of the medication when said diameter of said inlet tube is in said collapsed condition due to the lack of flow of the medication to the patient.

5        107. An empty detection system as set forth in claim 99 wherein said electronic controller deactivates said pump assembly when said diameter of said inlet tube is in said collapsed condition due to the lack of flow of the medication to the patient.

10        108. An empty detection system as set forth in claim 99 wherein said electronic controller deactivates said pump assembly when said diameter of said inlet tube is in said collapsed condition for more than one cycle of said pump assembly.

109. An integrated medication delivery system for delivering medication to a patient wherein the operation of said system can be tested using a testing instrument after assembly of said system, and said system can be completely sterilized by a sterilization fluid after testing, said system comprising:

5 a base housing;

a medication reservoir disposed about said base housing for storing the medication to be delivered to the patient;

a pump assembly supported by said base housing for delivering the medication to the patient, said pump assembly comprising a pump housing having a  
10 pump inlet and a pump outlet, wherein said pump inlet and said pump outlet alternate between an open and a closed state to deliver the medication the patient;

a port extending from said base housing, said port being in fluid communication with said medication reservoir and said pump assembly during sterilization to provide access for the sterilization fluid to flow into said medication  
15 reservoir and said pump assembly;

an actuator disposed in said base housing wherein said actuator is moveable between;

a disengaged position wherein said actuator is operatively disengaged from said pump inlet and said pump outlet to permit said pump inlet and said  
20 pump outlet to alternate between said open and closed states after assembly and during testing of the system, and

an engaged position where said actuator is operatively engaged to said pump inlet and said pump outlet to retain both said pump inlet and said

pump outlet in said open state during sterilization such that the sterilization fluid can penetrate into said medication reservoir, said pump inlet, said pump housing, and said pump outlet to completely sterilize said system; and at least one testing access port defined within said base housing and aligned with at least one of said pump inlet, said pump outlet, and said actuator to provide access for the testing instrument to move said actuator between said disengaged position and said engaged position such that said pump inlet and said pump outlet can alternate between said open and closed states after assembly and during testing of said system, and such that said pump inlet and said pump outlet can be retained in said open state after said system has been tested to prepare said system for sterilization.

110. A system as set forth in claim 109 wherein said at least one testing access port is further defined as first, second, and third testing access ports wherein said first testing access port is aligned with said pump inlet, said second testing access port is aligned with said pump outlet, and said third testing access port is aligned with said actuator for providing access to the testing instrument to move said actuator into said engaged position.

111. A system as set forth in claim 110 further comprising a first pinch lever disposed at said pump inlet that is normally-biased to maintain said pump inlet in said closed state, and a second pinch lever disposed at said pump outlet that is normally-biased to maintain said pump outlet in said closed state.

112. A system as set forth in claim 111 wherein said first testing access port is aligned with said first pinch lever such that said first pinch lever is adapted to



be engaged by the testing instrument thereby forcing said first pinch lever away from said pump inlet and said pump inlet into said open state, and said second testing access port is aligned with said second pinch lever such that said second pinch lever is adapted to be engaged by the testing instrument thereby forcing said  
5 second pinch lever away from said pump outlet and said pump outlet into said open state.

113. A system as set forth in claim 112 wherein said actuator is moved into said engaged position after said first and second pinch levers have been forced away from said pump inlet and said pump outlet, respectively, by the testing  
10 instrument.

114. A system as set forth in claim 112 wherein each of said first and second pinch levers comprise lever guides that are adapted to be engaged by the testing instrument upon insertion of the testing instrument into said first and second testing access ports.

15 115. A system as set forth in claim 109 further comprising a first pinch lever disposed at said pump inlet that is normally-biased to maintain said pump inlet in said closed state, and a second pinch lever disposed at said pump outlet that is normally-biased to maintain said pump outlet in said closed state.

116. A system as set forth in claim 115 wherein said actuator is  
20 operatively disengaged from said first and second pinch levers in said disengaged position such that said pump inlet and said pump outlet can alternate between said open and closed states after assembly and during testing of the system.

117. A system as set forth in claim 116 wherein said actuator is operatively engaged to said first and second pinch levers in said engaged position such that said pump inlet and said pump outlet are retained in said open state during sterilization and after said system has been tested.

5 118. A system as set forth in claim 117 wherein said at least one testing access port is aligned with at least one of said first pinch lever, said second pinch lever, and said actuator to provide access for the testing instrument to move said actuator between said disengaged position and said engaged position.

10 119. A system as set forth in claim 116 wherein said actuator comprises a base portion and at least one engagement arm extending from said base portion with said at least one engagement arm of said actuator operatively engaging and disengaging said first and second pinch levers.

15 120. A system as set forth in claim 119 wherein said at least one testing access port is aligned with said at least one engagement arm of said actuator to provide access for the testing instrument to move said actuator between said disengaged position and said engaged position.

20 121. A system as set forth in claim 119 wherein said at least one engagement arm is further defined as a first and second engagement arm with said first engagement arm of said actuator operatively engaging and disengaging said first pinch lever, and said second engagement arm of said actuator operatively engaging and disengaging said second pinch lever.

122. A system as set forth in claim 109 further comprising a plunger disposed within said port to displace said actuator from said engaged position such

that said pump inlet and said pump outlet can alternate between said open and closed state to deliver the medication to the patient after assembly, testing, and sterilization of said system.

123. A system as set forth in claim 109 further comprising a motor and an  
5 electronic controller mounted to said base housing for controlling an amount of the medication to be delivered to the patient.

124. A system as set forth in claim 123 further comprising at least one  
controller access port defined within said base housing and aligned with said  
electronic controller to provide access for a second testing instrument that causes  
10 said electronic controller to activate said motor such that said motor is powered to alternate said pump inlet and said pump outlet between said open and closed states after assembly and during testing of the system.

125. An integrated medication delivery system for delivering medication to a patient wherein said system is suitable for carrying by the patient and comprises:

a base housing;

5 a carrying strap mounted within said base housing for the carrying of said system by the patient;

a medication reservoir disposed about said base housing for storing the medication to be delivered to the patient;

a pump assembly supported by said base housing for delivering the medication to the patient, said pump assembly comprising a pump housing having a pump inlet and a pump outlet, wherein said pump inlet and said pump outlet alternate between an open and a closed state to deliver the medication the patient;

a port extending from said base housing, said port being in fluid communication with said medication reservoir, said pump assembly, and the patient to provide access for the medication to be delivered to the patient; and

an integral storage cavity defined within said base housing wherein said carrying strap is at least partially disposed in said integral storage cavity and at least partially extends from said integral storage cavity to interact with the patient for carrying said system.

20 126. A system as set forth in claim 125 wherein said base housing is further defined as a bottom housing and a top housing mounted to said bottom housing.

127. A system as set forth in claim 126 further comprising a reservoir casing disposed between said bottom and top housings, said reservoir casing at least partially surrounding said medication reservoir to protect the medication to be delivered to the patient as the patient carries said system.

5 128. A system as set forth in claim 126 further comprising a plurality of cavity walls extending from said bottom housing to define said integral storage cavity between said bottom and top housings.

129. A system as set forth in claim 128 wherein said plurality of cavity walls is further defined as a front wall, a rear wall, and first and second side walls  
10 extending between said front and rear walls to support said front and rear walls and to define said integral storage cavity.

130. A system as set forth in claim 129 further comprising at least one strap slot defined within said front wall such that at least a portion of said carrying strap extends from said integral storage cavity through said strap slot for access of  
15 said portion by the patient when desired.

131. A system as set forth in claim 130 wherein the patient manipulates said portion of said carrying strap to pull a length of said carrying strap from said integral storage cavity.

132. A system as set forth in claim 131 wherein said carrying strap is  
20 retractable into said integral storage cavity after said length has been pulled from said integral storage cavity by the patient.

133. A system as set forth in claim 125 further comprising a clip connecting opposing ends of said carrying strap such that said carrying strap is adjustable.

134. A system as set forth in claim 125 in combination with a system  
5 mounting clip extending from an exterior facing of said base housing that is adapted to be mounted to a belt of the patient.

135. A system as set forth in claim 125 wherein said carrying strap is further defined as a shoulder strap that is adapted to suspend from a shoulder of the patient for carrying said system.

136. A method of controlling an integrated medication delivery system that is used to deliver medication to a patient wherein the system includes an electronic controller, at least one control button, a patient label, and a removable overlay label disposed on top of the patient label for controlling an amount of the medication to be delivered to the patient, said method comprising the steps of:

selecting the amount of the medication in accordance with a first set of explanatory indicia on the removable overlay label;

locking the system such that the selected amount of the medication to be delivered to the patient is unable to be modified;

removing the removable overlay label to reveal the patient label; and

operating the system in accordance with a second set of explanatory indicia on the patient label.

137. A method as set forth in claim 136 wherein the step of operating the system in accordance with the second set of explanatory indicia comprises the step of deactivating the system to stop delivery of the medication to the patient.

138. A method as set forth in claim 137 wherein the step of operating the system in accordance with the second set of explanatory indicia further comprises the step of activating the system to re-start delivery of the medication to the patient after the system has been deactivated.

139. A method as set forth in claim 136 wherein the step of operating the system in accordance with the second set of explanatory indicia comprises the step of requesting an additional amount of the medication relative to the selected amount.

140. A method as set forth in claim 139 wherein the step of requesting an additional amount of the medication relative to the selected amount is further defined as actuating the control button to request the additional amount of the medication.

5 141. A method as set forth in claim 136 wherein the step of selecting the amount of the medication is further defined as selecting a flow rate for the medication.

142. A method as set forth in claim 136 wherein the step of locking the system comprises the step of modifying a functionality of the control button such  
10 that the functionality of the control button is different when the removable overlay label is displayed on the system as compared to when the patient label is displayed on the system.

143. A method as set forth in claim 142 wherein the control button is at least tri-functional when the removable overlay label is displayed on the system and  
15 the step of modifying the functionality of the control button is further defined as converting the functionality of the control button from at least tri-functional to bi-functional after the system has been locked and the patient label is displayed on the system.

144. A method as set forth in claim 136 wherein the system further  
20 includes an electronic display that presents a readable output and said method further comprises the step of correlating the readable output of the electronic display with the removable overlay label and the patient label.



145. A method as set forth in claim 144 wherein the step of correlating the readable output of the electronic display is further defined as presenting a first readable output linked with the first set of explanatory indicia when the removable overlay label is displayed, and presenting a second readable output linked with the  
5 second set of explanatory indicia after the system has been locked.

146. A method as set forth in claim 136 further comprising the steps of mounting the patient label to the system and mounting the removable overlay label on top of the patient label to at least partially cover the patient label.

147. A control system for an integrated medication delivery system, the integrated medication delivery system having a pump assembly, the pump assembly including a pump housing and a motor for delivering medication to a patient, the control system comprising:

5 an electronic controller for controlling operation of the integrated medication delivery system;

a motor control circuit having a first switch and being coupled between the electronic controller and the motor, the first switch having an open state and a closed state; and,

10 a watchdog circuit coupled to the electronic controller, the watchdog circuit including a monitor circuit and a second switch, the second switch having an open state and a closed state and being coupled to the first switch, wherein the monitor circuit is adapted to detect an abnormal condition in the control system and to responsively turn the second switch off if the abnormal condition is detected, and  
15 wherein the motor control circuit is adapted to receive control signals from the electronic controller and to responsively supply power to the motor by placing the first switch in one of the open and closed states, wherein power is supplied to the motor if the first and second switches are in the closed state.

148. A control system, as set forth in claim 147, wherein the first switch is  
20 a field effect transistor.

149. A control system, as set forth in claim 147, wherein the second switch is a field effect transistor.

150. A control system, as set forth in claim 147, wherein the electronic controller includes a microprocessor.

151. A control system, as set forth in claim 147, including at least one control button coupled to the electronic controller and being adapted to receive a  
5 desired flow rate from a user.

152. A control system, as set forth in claim 151, wherein the electronic controller is adapted to receive the desired flow rate and to respectively control energization of the motor to deliver medication at the desired flow rate.

153. A control system, as set forth in claim 152, wherein a revolution of  
10 the motor delivers a set amount of medication, and wherein the electronic controller calculates an amount of time between each revolution of the motor as a function of the desired flow rate.

154. A control system, as set forth in claim 153, wherein the motor control circuit includes a motor sensor coupled to the motor and being adapted to detect a  
15 revolution of the motor and to responsively generate a motor revolution signal in response to completion of the motor revolution.

155. A control system, as set forth in claim 154, wherein the electronic controller is adapted to reset the watchdog circuit prior to sending control signals to the motor control circuit to energize the motor and wherein the watchdog circuit is  
20 adapted to place the second switch in the closed state if two motor revolution signals are received without the watchdog circuit being reset.

156. A control system, as set forth in claim 155, wherein the monitor circuit includes first and second flip-flops, the first flip-flop being coupled to the

electronic controller and the second flip-flop, and the second flip-flop being coupled to the second switch.

157. A control system, as set forth in claim 156, wherein the electronic controller supplies power to the first and second flip-flops.

5 158. A control system, as set forth in claim 157, wherein the electronic controller shuts off power to the first and second flip-flops between revolutions of the motor.

159. A control system, as set forth in claim 157, wherein the electronic controller resets the watchdog circuit by shutting off and restoring power to the first  
10 and second flip-flops.

160. A control system, as set forth in claim 154, wherein the electronic controller is adapted to track a time after a motor control signal has been sent and to enter a disabled state if the time between the sent motor control signal and the received motor revolution signal exceeds a predetermined threshold.

15 161. A control system, as set forth in claim 147, further comprising a key which is adapted to be coupled to the electronic controller only during initial start-up and wherein the electronic controller is adapted to initialize upon start-up only if the key is present.

162. A control system, as set forth in claim 147, wherein the electronic  
20 controller includes a microprocessor and a crystal coupled to the microprocessor and the microprocessor includes an internal oscillator, wherein the electronic controller is adapted to compare a first frequency associated with the internal oscillator and a second frequency associated with the internal oscillator.

163. A control system, as set forth in claim 162, wherein the electronic controller is adapted to compare a difference between the first and second frequencies and enter a disabled state if the difference is greater than a predetermined threshold.

164. A circuit for use in a control system for an integrated medication delivery system, the integrated medication delivery system having a pump assembly, the pump assembly including a pump housing and a motor for delivering medication to a patient, the circuit comprising:

5 a motor control circuit having a first switch and being coupled between the electronic controller and the motor, the first switch having an open state and a closed state; and,

a watchdog circuit coupled to the electronic controller, the watchdog circuit including a monitor circuit and a switch, the second switch having an open state and  
10 a closed state and being coupled to the first switch, wherein the monitor circuit is adapted to detect an abnormal condition in the control system and to responsively turn the second switch off if the abnormal condition is detected, and wherein the motor control circuit is adapted to receive control signals from the electronic controller and to responsively supply power to the motor by placing the first switch  
15 in one of the open and closed states, wherein power is supplied to the motor if the first and second switches are in the closed state.

165. A circuit, as set forth in claim 164, wherein the first switch is a field effect transistor.

166. A circuit, as set forth in claim 164, wherein the second switch is a  
20 field effect transistor.

167. A circuit, as set forth in claim 164, wherein the motor control circuit includes a motor sensor coupled to the motor and being adapted to detect a

revolution of the motor and to responsively generate a motor revolution signal in response to completion of the motor revolution.

168. A circuit, as set forth in claim 167, wherein the electronic controller is adapted to reset the watchdog circuit prior to sending control signals to the motor control circuit to energize the motor and wherein the watchdog circuit is adapted to  
5 place the second switch in the open state if two motor revolution signals are received without the watchdog circuit being reset.

169. A circuit, as set forth in claim 168, wherein the monitor circuit includes first and second flip-flops, the first flip-flop being coupled to the electronic  
10 controller and the second flip-flop, and the second flip-flop being coupled to the second switch.

170. A circuit, as set forth in claim 169, wherein the electronic controller supplies power to the first and second flip-flops.

171. A circuit, as set forth in claim 170, wherein the electronic controller  
15 shuts off power to the first and second flip-flops between revolutions of the motor.

172. A circuit, as set forth in claim 170, wherein the electronic controller resets the watchdog circuit by shutting off and restoring power to the first and second flip-flops.

173. A circuit, as set forth in claim 164, further comprising a key which is  
20 adapted to be coupled to the electronic controller only during initial start-up and wherein the electronic controller is adapted to initialize upon start-up only if the key is present.

174. A circuit, as set forth in claim 173, wherein the electronic controller includes a microprocessor and a crystal coupled to the microprocessor and the microprocessor includes an internal oscillator, wherein the electronic controller is adapted to compare a first frequency associated with the internal oscillator and a  
5 second frequency associated with the internal oscillator.

175. A circuit, as set forth in claim 174, wherein the electronic controller is adapted to compare a difference between the first and second frequencies and enter a disabled state if the difference is greater than a predetermined threshold.



176. A control system for an integrated medication delivery system,  
comprising:

an electronic controller for controlling operation of the integrated medication  
delivery system; and,

5 a key which is adapted to be coupled to the electronic controller only during  
initial start-up and wherein the electronic controller is adapted to initialize upon  
start-up only if the key is present.

177. A control system for an integrated medication delivery system,  
comprising:

an electronic controller for controlling operation of the integrated medication  
delivery system, the electronic controller including a microprocessor having an  
5 internal oscillator; and,

a crystal coupled to the microprocessor, wherein the electronic controller is  
adapted to compare a first frequency associated with the internal oscillator and a  
second frequency associated with the internal oscillator.

178. A control system, as set forth in claim 177, wherein the electronic  
10 controller is adapted to compare a difference between the first and second  
frequencies and enter a disabled state if the difference is greater than a  
predetermined threshold.